Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Charles P. Kocoras	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	00 C 1475	DATE	5/2/2001
CASE TITLE	Pfizer, Inc. et al vs. Novopharm Ltd.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ■ Status hearing set for 9/5/2001 at 9:30 a.m..

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Ruling held. **ENTER MEMORANDUM OPINION:** Defendant's motion (Doc 35-1) to strike plaintiffs' jury demand is granted. The jury demand is stricken from the complaint. The Court will rule on pending motion (Doc 47-1) to compel by mail. By agreement of the parties, those parties with the burden of proof are given to June 4, 2001 to tender their experts' reports. Depositions of said experts to be completed by July 3, 2001. Rebuttal experts' reports to be tendered by July 20, 2001. Depositions of said experts to be completed by August 20, 2001. So ordered.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices
	No notices required.		MAY 03 2001
	Notices mailed by judge's staff.		date docketed
	Notified counsel by telephone.		docketing deputy initials
✓	Docketing to mail notices.		date mailed notice
	Mail AO 450 form.		
	Copy to judge/magistrate judge.		
SCT	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials

Document Number

31

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC. and PFIZER TECHNOLOGIES LIMITED, Plaintiff,	)	
vs.	)	00 C 1475
NOVOPHARM LIMITED, Defendant.	)	

MEMORANDUM OPINION

CHARLES P. KOCORAS, District Judge:

This matter is before the court on the motion of Defendant Novopharm Limited to strike Plaintiffs' jury demand. For the reasons set forth below, the motion is granted.

BACKGROUND

Plaintiffs Pfizer, Inc. and Pfizer Technologies Limited (collectively, "Pfizer") are the owner and beneficial owner, respectively, of U.S. Patent No. 4,404,216 (the "'216 patent") for an antifungal compound known as fluconazole. Pfizer markets fluconazole under the trade name Diflucan®. In January of 2000, Defendant Novopharm Limited ("Novopharm") submitted an Abbreviated New Drug Application (the "ANDA") to the U.S. Food and Drug Administration in an effort to obtain

approval to engage in the commercial manufacture, use or sale of fluconazole tablets prior to the expiration of the '216 patent. The ANDA included a Paragraph IV Certification containing Novopharm's opinion that Pfizer's '216 patent was invalid (the "ANDA"). See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Shortly after it learned that the ANDA and Paragraph IV Certification had been filed, Pfizer filed this lawsuit. The complaint alleges a violation of 35 U.S.C. § 271(e)(2), which deems the submission of a Paragraph IV Certification to be an act of infringement. Pfizer does not allege that Novopharm has engaged in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of its generic fluconazole product, as would be required for Pfizer to recover damages under 35 U.S.C. § 271(e)(4). The only relief Pfizer seeks – and the only relief to which it is entitled based on the submission of the Paragraph IV ANDA – is equitable: (1) an order declaring the '216 patent infringed; (2) an order providing that any FDA approval of Novopharm's ANDA become effective after the expiration of the '216 patent; (3) an injunction against the commercial manufacture, use, offer for sale, or sale of fluconazole tablets by Novopharm before the expiration of the '216 patent; and (4) an award of attorneys fees and costs. Novopharm answered the complaint, raising the affirmative defense of invalidity of Pfizer's patent.

The complaint contains a jury demand. Novopharm has moved to strike the demand based on the purely equitable nature of Pfizer's claims for relief. Pfizer counters that by asserting the affirmative defense of patent invalidity, Novopharm has raised a legal issue which Pfizer has a Seventh Amendment right to try before a jury. It has opposed the motion to strike on this basis.

DISCUSSION

The Seventh Amendment to the United States Constitution guarantees litigants the right to a jury trial in "Suits at common law." In determining whether a statutory cause of action encompasses a right of trial by jury, we apply the two-prong test set forth in Tull v. U.S., 481 U.S. 412, 417, 107 S. Ct. 1831 (1987). "First, we compare the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity. Second, we examine the remedy sought and determine whether it is legal or equitable in nature." Id. at 417-18 (citations omitted).

In In re Lockwood, 50 F.3d 966 (1995), the Federal Circuit addressed at length the issue of whether the plaintiff in a suit for a declaratory judgment of patent invalidity was entitled to a jury trial. Patentee Lawrence Lockwood had filed suit against American Airlines, alleging that the company's computerized reservation system infringed his patents relating to self-service terminals and automatic ticket systems. Lockwood sought both damages and injunctive relief, and made a timely jury

demand. American counterclaimed for a declaratory judgment of noninfringement and of invalidity and unenforceability of Lockwood's patents. American eventually obtained a dismissal of Lockwood's infringement claims such that the only remaining cause of action was American's counterclaim for a declaratory judgment of invalidity of the patents. American then moved to strike Lockwood's jury demand, and the district court granted its motion.

Lockwood petitioned the Federal Circuit for a writ of mandamus directing the district court to reinstate his jury demand. Applying the Tull test, the Court sought "a single historical analog" for an action for a declaratory judgment of invalidity, "taking into consideration the nature of the cause of action and the remedy as two important factors." 50 F.3d at 972, n. 6 (quoting Tull, 481 U.S. at 421, n. 6). After examining the history of adjudication of patent validity, the court found this analog in a lawsuit for patent infringement in which the affirmative defense of invalidity has been pled. Id. at 974. In 18th-century patent infringement actions, the court explained,

> [t]he choice of forum and remedy, and thus of the method of trial, was left with the patentee....If the patentee sought only damages, the patentee brought an action at law; in such a case, the defense of invalidity was tried to the jury, assuming that a jury had been demanded. However, if the patentee facing past acts of infringement nevertheless sought *only* to enjoin future acts of infringement, the patentee could only bring a suit in equity, and the defense of invalidity ordinarily would be tried to the bench. Under both English and American jurisprudence, then, it was the patentee who decided in the first instance whether a jury trial on the

factual questions relating to validity would be compelled. Id. at 976 (citations omitted).

In the modern suit for declaratory judgment of invalidity, the court noted, the parties positions are "inverted" such that the patentee, as the defendant, can no longer control the method of trial by varying the relief it seeks. Id. at 974-75. But because the patentee would historically have had such control, the court held that it could not, "consistent with the Seventh Amendment, deny Lockwood that same choice [of trial method] merely because the validity of his patents comes before the court in a declaratory judgment action for invalidity rather than as a defense in an infringement suit." Id. at 976. The court therefore granted the plaintiff's petition for a writ of mandamus and directed the district court to reinstate the jury demand.

The Supreme Court agreed to review Lockwood, but it eventually vacated the Federal Circuit's opinion without comment after Lockwood withdrew its jury demand. See American Airlines, Inc. v. Lockwood, 116 S. Ct. 29 (1995); Barry S. Wilson, Patent Invalidity and the Seventh Amendment: Is the Jury Out?, 34 San Diego L. Rev. 1787, 1796 (1997). Thus Lockwood is not technically binding on this Court. Nonetheless, in combination with the concordant unpublished opinion in In re SGS Thomson v. Microelectronics, 60 F.3d 839, reh'g and reh'g en banc denied, 61 F.3d 862, cert. denied sub nom. International Rectifier v. SGS-Thomson Microelectronics

Inc., 116 S. Ct. 336 (1995), Lockwood is persuasive as a "source of guidance" and as an indication of the Federal Circuit's likely position on the Seventh Amendment question. Christianson v. Colt Indus. Operating Corp., 870 F. 2d 1292, 1298-99, n. 7 (7th Cir. 1989).

At first blush, Lockwood and SGS-Thomson appear to support Pfizer's position that patent validity – no matter how raised and in what context – is a legal issue that may be tried to a jury as of right. However, neither Federal Circuit opinion addressed the situation presented in this case: patent invalidity raised only as an affirmative defense to an equitable action brought under 35 U.S.C. § 271(e)(2). Unlike the traditional patent infringement action under 35 U.S.C. § 271(a), which is based on the prior commercial manufacture, use or sale of a patented invention, a 271(e)(2)(A) action is premised solely on the defendant's submission to the FDA of an Abbreviated New Drug Application with a Paragraph IV Certification. The submission of a Paragraph IV ANDA is a "technical" or "artificial" act of infringement which Congress designated as such in order to "provide[] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir 1997); see also Bristol-Myers Squibb Co. v. Royce Labs, Inc., 69 F.3d 1130, 1135 (Fed. Cir. 1995). It is the nature of an infringement

action brought under § 271(e)(2)(a) that the allegedly infringing drug has not yet been marketed and therefore the question of infringement focuses on what the ANDA applicant will likely market if its application is approved by the FDA. Glaxo, 110 F.3d at 1569. Accordingly, the statute expressly precludes the plaintiff from recovering damages except in the rare situation where the defendant has already engaged in the commercial manufacture, use, or sale of the drug without FDA approval. See 35 U.S.C. § 271(e)(4). There is no allegation of prior manufacture, use, or sale of fluconazole by Novopharm in the complaint, and Novopharm has stipulated that such infringement has not occurred. (See Stipulation attached as Exh. 6 to Memorandum in Support of Defendant's Motion, at ¶¶ 4-6.) This is therefore a typical § 271(e)(2)(a) action in which "infringement" in the traditional sense has not yet occurred and the patentee is statutorily limited to prospective equitable relief.

Even under the non-precedential Lockwood analysis, the parties are not entitled to a jury trial in an infringement action of this sort. See Brian D. Coggio and Sandra A. Bresnick, The Right to a Jury Trial in Actions Under the Hatch-Waxman Act, 79 J. Pat. & Trademark Off. Soc'y 765, 782-85 (proposing that under prevailing case law a declaratory judgment claim premised solely on the filing of an ANDA is equitable, not legal, and no jury right attaches); but see Hoechst Marion Roussel v. Par Pharmaceutical Inc., 39 U.S.P.Q.2d 1363, 1364-65 (D.N.J. 1996) (arriving at opposite

conclusion). As the Federal Circuit observed in that case, "declaratory judgment actions are, for Seventh Amendment purposes, only as legal or equitable in nature as the controversies on which they are founded." The controversy in the instant case is not an inversion of a traditional infringement lawsuit as was the declaratory judgment suit in Lockwood. See 50 F.3d at 980. Rather, it is a controversy of recent vintage created by Congress for the specific purpose of posturing drug patent claims for adjudication *before* actual infringement occurs. As such, it is inherently equitable, and the remedies are limited accordingly.

This case is therefore more akin to Shubin v. United States District Court, 313 F.2d 250 (9th Cir.), cert. denied, 373 U.S. 936, 83 S. Ct. 1539 (1963) than it is to Lockwood. In Shubin, the alleged infringer sought a declaratory judgment of invalidity and the defendant patentee counterclaimed, seeking only injunctive relief. The parties later stipulated that no infringement had yet occurred. On these facts, the Ninth Circuit held that the parties had no right to a jury trial, since the only issue to be determined was the patentee's right to injunctive relief against future infringement. Id. at 251-52. "[*T*]*hreatened* infringement," the court held, was not a legal issue. Id. at 251 (emphasis in original). The Lockwood court considered Shubin and did not express disapproval of its holding. Rather, it found Shubin to be uniquely applicable to the situation where "[t]he patentee's counterclaim for a permanent injunction against

future infringement, paired with its stipulation to the absence of any claim for infringement damages, convinced the court that the issues in the case were purely equitable ones." We face an almost indistinguishable situation here.

Accordingly, we decline to find a Seventh Amendment right to a jury trial in this case. We are of the view that, in an action under § 271(e)(2) predicated solely on the filing of a Paragraph IV ANDA and the likely future infringement that will occur if that ANDA is approved, the issues before the court are purely equitable; the presence of an affirmative defense of invalidity does nothing to change this characterization. For this reason, and because the patentee in such a suit has no right to seek damages (it is limited by statute to only equitable relief), the patentee is not entitled to a jury trial in garden variety § 271(e)(2) infringement claims. See Tull, supra; see also Chauffeurs, Teamsters & Helpers, Local No. 391 v. Terry, 494 U.S. 558, 564 (1990) (right to a jury trial does not extend to suits in equity). We need not be concerned, therefore, that an inversion of the infringement action, in the form of a declaratory judgment claim, will somehow eliminate the patentee's historical choice of trial method. In other words, our holding does not deprive the patentee of a right *it would otherwise have* merely because the alleged infringer has sought declaratory relief. Cf. Beacon Theatres, Inc. v. Westover, 359 U.S. 500, 504, 79 S. Ct. 948 (1959) ("[I]f Beacon would have been entitled to a jury trial in a treble damages suit against Fox it cannot be deprived of that

right merely because Fox took advantage of the availability of declaratory relief to sue Beacon first.").

Pfizer admittedly has no right to a jury trial on its equitable claims for relief under § 271(e)(2). In the absence of any issue of past infringement for which damages could conceivably be recovered, we do not believe that Novopharm's invalidity defense alters this result in any way. Accordingly, Pfizer's demand for trial by jury is improper and must be stricken from the complaint.

CONCLUSION

For the foregoing reasons, Defendant's motion is granted. The jury demand is stricken from the complaint.

Charles P. Kocoras

Charles P. Kocoras
United States District Judge

Dated: May 2, 2001